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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,051	03/01/2002	Daniel S. Sitar	0030-0206P	8155
2292	7590	10/01/2003	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			SRIVASTAVA, KAILASH C	
		ART UNIT		PAPER NUMBER
		1651		
DATE MAILED: 10/01/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/085,051	SITAR ET AL.
	Examiner	Art Unit
	Dr. Kailash C. Srivastava	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07/07/2003 as Paper Number 7.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

1. Claims 1-10 are pending.

### ***Restriction/Election***

2. Applicants' election without traverse of Group I, Claims 1-10 and of species as "non-spermine/spermidine N'-acetyltransferase for prosecution filed June 12, 2003 as Paper Number 7 to election requirement in Office Action mailed May 19, 2003 as paper number 6 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

3. Claims 1-10 are examined on merits.

### **Objection To Specification**

4. The disclosure is objected to because of the following informalities:

Significant amounts of text appear to be missing at page 2 of the disclosure due to poor photocopying of an original, not submitted. Appropriate correction is required. Applicants are advised to be careful not to introduce any new matter while revising the application to eliminate the above-discussed deficiency in the disclosure. A substitute specification may be necessary.

### ***Claim Rejections - 35 U.S.C. § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

6. Claims 1-10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The recitation, "derived" in claims 1 and 10 renders those claims unclear as well as confusing, and therefore, indefinite. The term does not clearly define as to how similar a material should be to the base material to be called a derivative, i.e. the term does not define the metes and bounds of the claimed subject matter.
- Claim 1 is incomplete. Simply measuring the amount of an acetylated product does not indicate that the product was acetylated by said enzyme. The claim needs more steps such as contacting the sample containing the SSAT enzyme with a SSAT substrate. Also, a step is needed to compare the results with a standard curve. While there is no specific rule or

statutory requirement which specifically addresses the need for different steps outlined above, it is clear from the record and would be expected from conventional assay procedures that the substrate and enzyme are contacted under appropriate conditions of temperature, pH and concentrations of both enzyme and substrate, methods to obtain a standard curve, detection limits for the assay and methods for quantifying different reactants in said enzyme mediated reaction. Thus, the claims fail to particularly point out and distinctly claim the "complete" method since steps outlined above are missing from the claims. The metes and bounds of the claimed method are therefore not clearly established or delineated. Appropriate correction is required. Applicants are warned to be careful not to introduce any new matter while defining these steps in said claim.

All other claims depend directly or indirectly from the rejected, Claim 1 and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102/103***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless -*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

10. Claims 1-10 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Alvaro et al., (Can. J. Physiol. Pharmacol., 1998. Volume 76, Pages 701-706) with evidence provided by Koppel et al. (Biomedical Mass Spectrometry, 1985, Volume 12,

Pages 499-501) and Morgan (Polyamines, In Methods in Molecular Biology. 1997, Volume 79, Pages 3-30).

Alvaro et al. teach a method to determine the concentration of acetyl amantadine in urine samples from human subjects that were given up to 200 mg daily dose of amantadine. Urine samples were collected during 2-8 hours post amantadine application and samples were analyzed for acetyl amantadine by gas chromatography (Page 702, Column 1, Line 62 to Page 703, Column 1, Line 22). Samples analyzed for acetyl amantadine contained 200  $\mu$ L of 5 mg  $L^{-1}$  solution of acetanilide as an internal standard. To obtain standard curves, amantadine and acetyl amantadine were quantified by comparing the results obtained from urine samples from treated subjects with standard curves obtained by spiking blank samples with known quantities of amantadine (Page 703, Column 1, Lines 23-38. Alvaro et al. further teach that acetyltransferases other than arylamine acetyltransferases are responsible for the acetylation of amantadine to acetyl amantadine (Page 701, Column 2, Lines 40-42) and amantadine acetylation to acetyl amantadine is catalyzed by inducible acetyl transferase conjugating spermine/spermidine (Page 705, Column 1, Lines 33-37). Amantadine is a non-diaminopropane substituted spermine/spermidine N'-acetyltransferase substrate because structurally amantadine is an aromatic compound without a propane substitution (See, Koppel et al., Figure 1), whereas spermine, spermidine and diaminopropane do not comprise an aromatic ring (See, Morgan, Figure 1).

Thus, the referenced method deems to anticipate the claimed invention.

However, even if the referenced and claimed methods are not one and the same, and there is, in fact, no anticipation, the reference method would, nevertheless, have rendered the claimed method to identify a non-spermine/spermidine substrate for spermine/spermidine N'-acetyltransferase *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made because the reference discloses identification of said substrate for said enzyme through same steps and under same conditions as recited in the instantly claimed invention.

Thus, the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

In this rejection under 35 U.S.C. §§102(b)/ 103(a), Koppel et al. (Biomedical Mass Spectrometry, 1985, Volume 12, Pages 499-501) and Morgan (Polyamines, In Methods in Molecular Biology. 19, Volume 79, Pages 3-30) are cited to merely support that amantadine is a non-diaminopropane substituted spermine/spermidine N'-acetyltransferase (i.e., SSAT) substrate, and said references are not cited as prior art references.

## Conclusion

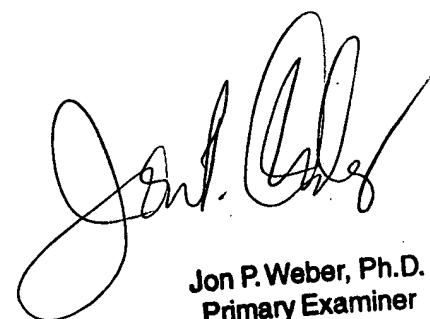
11. No Claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

~~Kailash C. Srivastava, Ph.D.~~  
Patent Examiner  
Art Unit 1651  
(703) 605-1196

September 30, 2003



Jon P. Weber, Ph.D.  
Primary Examiner